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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,303	10/07/2004	Kazunori Kataoka	2004-1437A	2024

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EXAMINER

HAQ, SHAFIQUL

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/507,303	KATAOKA ET AL.	
	Examiner	Art Unit	
	Shafiqul Haq	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/10/04, 12/23/05, 1/19/06 & 4/19/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendments filed April 19, 2006 is acknowledged and entered.
2. Claims 1-13 have been cancelled and new claims 14-24 have been entered.

Priority

3. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior applications in the first sentence of the specification including any foreign priority claimed.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 14-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claims 14, 20 and 21 recites the phrase "and the other group of said polymers have an integer less than that by at least 10". There are two integers "p" and "n" in formula (I) polymer. Therefore, its unclear what integer is referred by this phrase? There are two values of n in this claim. In line 13, n = 10-10,000 and in line 14 value of n is given as 50-10,000. Therefore, it is unclear the term "less than that" indicates less than what value of the integer. Also, value of n is given as a range (i.e. 50-10,000) for one polymer and its unclear the value of integer n of the other polymer is less (by at least 10) from what particular value in the range of the longer polymer (i.e. 50-10,000).

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7. Claims 22 and 23 recites the phrase "and the other has an integer less than that by at least". There are two integers "p" and "n" in formula (I) polymer. Therefore, its unclear what integer is referred by this phrase? There are two values of n in this claim. In line 13, $n = 10-10,000$ and in line 14 value of n is given as $50-10,000$. Therefore, it is unclear the term "less than that" indicates less than what value of the integer. Also, value of n is given as a range (i.e. $50-10,000$) for one polymer and its unclear the value of integer n of the other polymer is less (by at least 20, 50) from what particular value in the range of the longer polymer (i.e. $50-10,000$).
8. Claims 20 and 21 recites the phrase "which have an integer less than that said one group of polymers in step (A) by at least 10". There are two integers "p" and "n" in formula (Ia) and (Ib) polymer. Therefore, it's unclear what integer is referred by this phrase? Also, value of n is given as a range (i.e. $50-10,000$) for one polymer and its unclear the value of integer n of the other polymer is less (by at least 20, 50) from what particular value in the range of the longer polymer (i.e. $50-10,000$).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 14-19 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otsuka et al. (J. Am. Chem. Soc. 2001) in view of Pavey et al. (Biomaterials 1999).

Otsuka et al. disclose heterobifunctional poly(ethylene glycol)(PEG) derivatives containing mercapto group at one end to couple with gold surface and a functional group at other end to couple to ligand (Abstract and pages 8226-8227 and scheme 2 of page 8228). Otsuka et al also disclose method of preparation in which polymer is attached to gold surface (see synthesis of Au nanoparticles). Otsuka et al. disclose 70 ethylene glycol units ($M_n=3090$) which is within the value of 50-10,000 of present application.

Otsuka et al however, fail to disclose biosensor chip having two groups of polymer differing in chain length.

Pavey et al. disclose SPR slides in which combination of two groups of polymer having different polyethylene chain length are adhered (see abstract and lines 28-36 of left column, page 886). Pavey further disclose that protein (e.g. BSA) adhesion is reduced significantly when mixture of long and short chain polymer is used as compared with surfaces to which only one kind of polymer is adhered (page 888, lines 4-9 of right column and conclusion of page 890).

Therefore, given the above fact that using a mixture of two groups of long and short chain polymer significantly decrease protein adhesion to surface (Pavey et al.), it would have been obvious at the time of the invention to a person of ordinary skill in the art to use two groups of long and short chain polymer in the surface of Otsuka et

al with the expectation of reducing non-specific adhesion of proteins, with a reasonable expectation of success..

With respect to integer n of ethylene oxide repeat, the optimum number for n of the long and short chain polymer can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art to discover an optimum value of a result effective variable. “[W]here the general conditions of claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” Application of Aller, 220 F.2d 454,456, 105 USPQ 223, 235-236 (C.C.P.A. 1955). “No invention is involved in discovering optimum ranges of a process by routine experimentation.” Id. At 458,105 USPQ at 236-237. The “discovery of an optimum value of a result effective variable is a known process is ordinary within the skill of the art.” Application of Boesch, 617 F.2d 272,276,205 USPQ 215, 218-219 (C.C.P.A. 1980).

11. Claims 14-19 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kataoka et al. (US 6,927,033 B2) in view of Pavey et al. (Biomaterials 1999). .

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter

disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Kataoka et al. disclose polymer composition for forming surface of biosensor wherein a polymer represented by formula (I) is coupled onto the surface of the metal surface via the mercapto group present at one end of the polymer (Abstract and claims 1-4). The polymer of formula (I) anticipates formula (I) of claim 1 of present invention (Note that L1, L2= linker or bond). Regarding the claim language "it is a biosensor surface" in claim 1, it is the examiner's position that this is intended use language. Regarding claim 5, Kataoka discloses gold particle, metal oxide, semiconductor (see claim 2). Preparation in which polymer is attached to gold surface by contacting with gold surface is also disclosed (see example 1). Kataoka et al. also disclose average value of ethylene oxide repeat to be 10-20,000 which encompasses average value of 50-10,000 of present application.

Kataoka et al. however, fail to disclose biosensor chip having two groups of polymer differing in chain length.

Pavey et al. disclose SPR slides in which combination of two groups of polymer having different polyethylene chain length are adhered (see abstract and lines 28-36 of left column, page 886). Pavey further disclose that protein (e.g. BSA) adhesion is reduced significantly when mixture of long and short chain polymer is used as compared with surfaces to which only one kind of polymer is adhered (page 888, lines 4-9 of right column and conclusion of page 890).

Therefore, given the above fact that using a mixture of two groups of long and short chain polymer significantly decrease protein adhesion to surface (Pavey et al.), it would have been obvious at the time of the invention to a person of ordinary skill in the art to use two groups of long and short chain polymer in the biochip surface of Kataoka et al with the expectation of reducing non-specific adhesion of proteins, with a reasonable expectation of success.

With respect to integer n of ethylene oxide repeat, the optimum number for n of the long and short chain polymer can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Application of *Aller*, 220 F.2d 454,456, 105 USPQ 223, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." *Id.* At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable is a

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known process is ordinary within the skill of the art." Application of Boesch, 617 F.2d 272,276,205 USPQ 215, 218-219 (C.C.P.A. 1980).

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 14-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/509,576 in view of Pavey et al. (Biomaterials 1999). Although the conflicting claims are not identical, they are not patentably distinct from each other because polymers of general formula (I) are the same as the polymer (I) of copending application. In the formula (I) of copending application, when W^2 -PEG- W^1 -L is same in $(X-W^2\text{-PEG-}W^1\text{-L})_x$ and $(Y-W^2\text{-PEG-}W^1\text{-L})_y$, and when Y stands for functional moiety X, the polyethylene glycol (PEG) modified nanoparticle can be viewed as a nanoparticle surface linked with a PEG linker in which the other end of the linker has a functional moiety capable of binding to biomolecular target (note that W^1 and W^2 can be a single bond and L stands for linker or linkage portion).

Copending application 10/509,576 disclose polymer composition having a mercapto group or trialkoxysilyl at one end and functional group or ligand at the other end. Preparation in which polymer is attached to gold surface by contacting with gold surface is also disclosed (see production examples 1-4 of pages 7-9). Copending application also disclose average value of ethylene oxide repeat to be 5-10,000. Method of producing biosensor chips with the polymer is also disclosed in this copending application (see claims 2, 4, 6 and 8).

Copending application however, fail to disclose biosensor chip having two groups of polymer differing in chain length.

Pavey et al. disclose SPR slides in which combination of two groups of polymer having different polyethylene chain length are adhered (see abstract and lines 28-36 of left column, page 886). Pavey further disclose that protein (e.g. BSA) adhesion is reduced significantly when mixture of long and short chain polymer is used as compared with surfaces to which only one kind of polymer is adhered (page 888, lines 4-9 of right column and conclusion of page 890).

Therefore, given the above fact that using a mixture of two groups of long and short chain polymer significantly decrease protein adhesion to surface (Pavey et al.), it would have been obvious at the time of the invention to a person of ordinary skill in the art to use two groups of long and short chain polymer in the biochip surface of copending application with the expectation of reducing non-specific adhesion of proteins, with a reasonable expectation of success..

With respect to integer n of ethylene oxide repeat, the optimum number for n of the long and short chain polymer can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Application of *Aller*, 220 F.2d 454,456, 105 USPQ 223, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." *Id.* At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable is a known process is ordinary within the skill of the art." Application of *Boesch*, 617 F.2d 272,276,205 USPQ 215, 218-219 (C.C.P.A. 1980).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 14-19 and 22-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,927,033 B2 in view of *Pavey et al.* (Biomaterials 1999). Although the conflicting claims are not identical, they are not patentably distinct from each other because polymers of general formula (I) of present application are the same as the polymer (I) of copending application. Claims in the above patent disclose polymer composition containing functional group for coupling to biosensor surface and to ligands, which are same as the functional group of present application. '033 patent

disclose average value of ethylene oxide repeat to be 10-20,000 which encompasses average value of 50-10,000 of present application.

'033 patent however, fail to disclose biosensor chip having two groups of polymer differing in chain length.

Pavey et al. disclose SPR slides in which combination of two groups of polymer having different polyethylene chain length are adhered (see abstract and lines 28-36 of left column, page 886). Pavey further disclose that protein (e.g. BSA) adhesion is reduced significantly when mixture of long and short chain polymer is used as compared with surfaces to which only one kind of polymer is adhered (page 888, lines 4-9 of right column and conclusion of page 890).

Therefore, given the above fact that using a mixture of two groups of long and short chain polymer significantly decrease protein adhesion to surface (Pavey et al.), it would have been obvious at the time of the invention to a person of ordinary skill in the art to use two groups of long and short chain polymer in the biochip surface of '033 patent with the expectation of reducing non-specific adhesion of proteins, with a reasonable expectation of success.

With respect to integer n of ethylene oxide repeat, the optimum number for n of the long and short chain polymer can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105

USPQ 223, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable is a known process is ordinary within the skill of the art." Application of Boesch, 617 F.2d 272,276,205 USPQ 215, 218-219 (C.C.P.A. 1980).

Response to Argument

15. Applicant's arguments filed 04/19/06 have been fully considered, and are persuasive to overcome the rejections of 10/19/05 under 35 USC 112, 35 USC 102 and 35 USC 103, but Applicants' amendment necessitated new ground of rejections which are presented in this office action.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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